



Berkshire West Area Prescribing Committee Policy Statement

Drug Name	0.45mg conjugated oestrogens and bazedoxifene acetate equivalent to 20mg bazedoxifene modified release tablets (Duavive®)		
Indication under review	Treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin containing therapy is not appropriate		
Policy No:	APC 148		
Date of Issue:	March 2017		
Review Date:	March 2020		
Policy Statement:	0.45mg conjugated oestrogens and bazedoxifene acetate equivalent to 20mg bazedoxifene modified release tablets (Duavive®) is not recommended for routine prescribing in primary care.		
Traffic Light Status	Brown		
Key Points considered:	<ul style="list-style-type: none"> • In a randomised controlled trial (RCT) of involving 332 women, at week 12, Duavive statistically significantly reduced the average daily number of moderate and severe hot flushes from baseline compared with placebo. • In another RCT (n= 664) in women with vulvar or vaginal atrophy, at week 12 there were statistically significant improvements compared with placebo in some but not all primary outcomes in the Duavive group. • The small number of women enrolled in the trials and short duration of exposure, the available safety data do not allow for assessment of whether the incidence of rare but important adverse events including cardiovascular or cerebrovascular events, venous thromboembolism or cancer (including breast or ovarian) are increased in women taking Duavive compared with placebo or other treatments. • The APC would consider reviewing their recommendation in light of new data on longterm safety of this treatment. 		
References	NICE Evidence Summary published 22 nd December 2016 available at nice.org.uk/guidance/es3		
Date taken to APC:	1 st March 2017		
Date Ratified by GPMOC on Behalf of the Board:	15 th March 2017		

Berkshire West Area Prescribing Policies serve as a guide to clinicians. This does not overrule the clinical or budgetary responsibility of clinicians when considering treatment for individual patients.

Brown	Green	Amber	Red
These drugs have been reviewed and are not considered a cost effective use of scarce NHS resources	Medicines suitable for routine use. Primary care prescribers take full responsibility for prescribing	Medicines that should be initiated by a specialist and can be continued in primary care under a shared care agreement.	Medicines which should be prescribed by specialists only